

R E M A R K S

Claims 1 to 9 and 12 to 20 presented with applicants' paper dated June 05, 2006, are currently pending.

The Examiner rejected Claims 1 to 9 and 12 to 20 under 35 U.S.C. §102(b) as being anticipated by the teaching of *Denzinger et al.* (US 4,402,937).

It is well settled that anticipation under Section 102 can be found only if a reference shows exactly what is claimed, i.e.

- all material elements of the invention as claimed must be found in one prior art source,<sup>1)</sup>
- the elements must be shown in the reference in as much detail as is contained in the claim,<sup>2)</sup> and
- the elements must be shown in the reference in the part-to-part relationship which is set forth in the claim.<sup>3)</sup>

Notably, the fact that claimed subject matter may be encompassed by a generic disclosure does not, by itself, establish obviousness of the claimed subject matter.<sup>4)</sup> Anticipation is the ultimate or epitome of obviousness,<sup>5)</sup> and anticipation under Section 102 requires therefore more than a generic disclosure which encompasses claimed subject matter.

The Examiner argued, on the one hand, that "*Denzinger meets the limitations of the instant claims,*"<sup>6)</sup> and acknowledged, on the other hand, that the reference "*fails to exemplify the claimed relationship,*"<sup>7)</sup> i.e. the requirement of applicants' Claim 1 that

*at the time of mixing the concentration c of the aqueous polyvinylpyrrolidone, based on the total amount of polyvinylpyrrolidone and water, and the K value of polyvinylpyrrolidone obeys the fol-*

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1) Cf. *In re Marshall*, 577 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Kalm*, 378 F.2d 959, 154 USPQ 10 (CCPA 1967).

2) Cf. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989).

3) Cf. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

4) Cf. *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); see also *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 9 USPQ2d 1962 (Fed. Cir. 1989), which holds that a genus does not inherently disclose all species; and *In re Jones*, 958 F.3d 347, 21 USPQ2d 1614 (Fed. Cir. 1992), which holds that a genus does not render all species that happen to fall within the genus obvious.

5) Cf. *In re Grose*, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979).

6) Office action page 3, line 4.

7) Office action page 4, line 1.

lowing relation:

$$c > 100 \times [0.1 + 8 : (K + 5)]$$

where  $c$  is stated in % by weight, and the Fikentscher  $K$  value is in the range from 10 to 100.

The teaching of *Denzinger et al.* can clearly not be deemed to show all elements of applicants' claims, and to show the elements of applicants' claims in in as much detail as is contained in applicants' claims since, as explained in detail in applicants' reply dated April 30, 2004,<sup>8)</sup> and conceded by the Examiner, the reference fails to show the relationship between the concentration and the Fikentscher  $K$  value of the PVP which is required in accordance with applicants' invention.<sup>9)</sup> The teaching of *Denzinger et al.*, can, accordingly, not be deemed to anticipate applicants' invention within the meaning of Section 102(b), and it is respectfully urged that the respective rejection be withdrawn. Favorable action is solicited.

Further, the Examiner rejected Claims 1 to 9 and 12 to 20 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of *Denzinger et al.* (ibid.). The Examiner argued in this context that a person "having ordinary skill in the art would have been motivated to optimize the starting concentration of the PVP by routine experimentation that would be expected to produce a PVP solution that is at least 50% higher in stability than that of the state of the prior art."<sup>10)</sup>

When applying 35 U.S.C. §103, it is inter alia required that the references be considered as a whole, that the references suggest the desirability and thus the obviousness of making the claimed combination, and that the references be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.<sup>11)</sup> When determining whether a claimed invention meets the provisions of Section 103 it is, therefore, necessary that the decisionmaker return to the time at which the invention was made.<sup>12)</sup> An evaluation of the

8) The respective paper is herewith incorporated by reference.

9) Cf. also applicants' respective arguments presented in the Brief on Appeal filed on August 12, 2004. The respective paper is herewith incorporated by reference.

10) Office action page 4, lines 7 to 9.

11) *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

12) *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988), cert. denied, 488 U.S. 825 (1988); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 16 USPQ2d 1923 (Fed. Cir. 1990).

teaching of *Denzinger et al.* following these tenets of patent law reveals that the reference fails to suggest the desirability, and thus the obviousness, of the claimed combination.

The teaching of *Denzinger et al.* contains nothing which suggests or implies that the concentration or the K value of the PVP has an impact on the stability of the product. To the contrary, according to the reference the increased stability of the product is a result of balancing the iodine:iodide ratio and the partition coefficient, and of carrying out the reaction of PVP and iodine in the presence of certain acids.<sup>13)</sup> A modification of the concentration of the PVP relative to the K value in order to achieve an improved stability of the product is neither suggested nor implied by the reference. As explained by the Courts, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.<sup>14)</sup> No such recognition is found or even suggested in the teaching of *Denzinger et al.* with regard to the concentration and/or the K value of the PVP.<sup>15)</sup> It is merely stated that higher PVP concentrations in the aqueous starting solution apply to PVP having low K values, and vice versa.<sup>16)</sup>

To establish a prima facie case of obviousness in a genus-species chemical composition situation, as in any other 35 U.S.C. 103 case, it is essential that there be some motivation or suggestion to make the claimed invention in light of the prior art teachings.<sup>17)</sup> "[A] proper analysis under §103 requires, inter alia, consideration of . . . whether the prior art would have suggested to those of ordinary

13) Cf. in particular col. 2, indicated line 63, to col. 3, indicated line 2, of *US 4,402,937*.

14) Cf. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.).

15) Applicants' paper dated June 05, 2006, which is herein incorporated by reference.

16) Col. 4, indicated lines 34 to 37, of *US 4,402,937*.

17) See, e.g., *In re Brouwer*, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996) ("[T]he mere possibility that one of the esters or the active methylene group-containing compounds . . . could be modified or replaced such that its use would lead to the specific sulfoalkylated resin recited in claim 8 does not make the process recited in claim 8 obvious "unless the prior art suggested the desirability of [such a] modification" or replacement.") (quoting *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

skill in the art that they should make the claimed composition or device, or carry out the claimed process."<sup>18)</sup> Regardless of the type of disclosure, the prior art must provide some motivation to one of ordinary skill in the art to make the claimed invention in order to support a conclusion of obviousness. "The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art."<sup>19)</sup> The teaching of *Denzinger et al.* does not provide the necessary motivation to employ an aqueous PVP solution wherein the K value of the PVP and the concentration of the solution meet the particular relation which is required in accordance with applicants' invention, and the Examiner's position that "[o]ne having ordinary skill in the art would have been motivated to optimize the starting concentration of the PVP by routine experimentation"<sup>10)</sup> is therefore deemed to be in error.

The Examiner criticized the comparative data presented by applicants with Dr. Dobrawa's Declaration dated May 29, 2006, for failing to include "comparable data from *Denzinger*."<sup>20)</sup> Applicants' herewith submit a further Declaration supplementing investigations into procedures in which aqueous PVP solutions containing

- 28% by weight of a PVP having a K value of 30, corresponding to Example 1 of *Denzinger et al.*,<sup>21)</sup> and
- 50% by weight of a PVP having a K value of 12, corresponding to Example 3 of *Denzinger et al.*,<sup>22)</sup>

were employed as starting material. The data and observations reported in the Declaration corroborate that an adjustment of the PVP concentration, relative to the K value thereof, in accordance with the relation referenced in applicants' claims, not only improves the weight percentage of available iodine of the product but also facilitates the procedure. When the PVP concentration was adjusted in the

18) *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

19) *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). See also *Hodosh v. Block Drug Co.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

20) Office action page 5, lines 7 to 11.

21) Cf. "Comp. 4" in the table on page 5 of Dr. Dobrawa's Declaration dated January 17, 2007.

22) Cf. "Comp. 5" in the table on page 5 of Dr. Dobrawa's Declaration dated January 17, 2007.

manner which is required in accordance with applicants' invention sedimentation was avoided and homogeneous mixing was possible,<sup>23)</sup> and iodine sublimation in the course of the process was avoided.<sup>24)</sup>

The data and explanations further corroborate that the teaching of *Denzinger et al.* is insufficient to render applicants' invention prima facie obvious within the meaning of Section 103(a). Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is therefore respectfully solicited.

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23) Cf. the data pertaining to Example 4 and Example Comp. 4 and Dr. Dobrawa's explanations on page 5 of the Declaration.

24) Cf. the data pertaining to Example 5 and Example Comp. 5 and Dr. Dobrawa's explanations on page 5 of the Declaration.